IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SMITH KLINE & FRENCH LABORATORIES, LTD, and SMITHKLINE BEECHAM CORP., d/b/a GLAXOSMITHKLINE, Plaintiffs, v. TEVA PHARMACEUTICALS USA, INC., Defendant.	Civil Action No. 05-197 GMS

ANSWER AND COUNTERCLAIMS OF DEFENDANT TEVA PHARMACEUTICALS USA, INC.

Defendant Teva Pharmaceuticals USA, Inc., ("Teva") answers the Complaint of Smith Kline & French Laboratories, Ltd, and SmithKline Beecham Corp., d/b/a GlaxoSmithKline, ("GSK") as follows:

1. Teva admits that plaintiffs purport to assert the claims set forth in Paragraph 1 of the Complaint. Teva denies that plaintiffs' claims are valid or have merit. Teva admits that it has filed an Abbreviated New Drug Application ("ANDA") seeking the approval of its ropinirole hydrochloride tablets. Teva admits that the act, as alleged arises under the patent laws of the United States.

2. Teva states that it is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 2 of the Complaint, and on that basis denies each and every one of the allegations set forth therein.

3. Teva states that it is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 3 of the Complaint, and on that basis denies each and every one of the allegations set forth therein.

4. Teva states that it is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 4 of the Complaint, and on that basis denies each and every one of the allegations set forth therein.

5. Teva admits the allegations set forth in Paragraph 5 of the Complaint.

6. Teva admits that this Court has jurisdiction over plaintiffs' claims pursuant to Title 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

7. Teva admits that this Court has jurisdiction over Teva for the purposes of this action.

8. Teva admits that venue is proper in this district pursuant to 28 U.S.C. §§ 1391(b) and 1400(b).

9. Teva admits that United States Patent No. 4,452,808 (the "'808 patent") is entitled "4-Aminoalkyl-2(3H)-Indolones," and states on its face that it was issued on June 5, 1984, identifying Gregory Gallagher, Jr., as the inventor. Teva further admits that the '808 patent states on its face that it was assigned to SmithKline Beckman Corporation. Teva admits that the '808 patent purports to claim certain 4-aminoalkyl-2(3H)-indolone compounds and pharmaceutical compositions. Teva denies that the claims of the '808 patent are valid and enforceable. Teva states that it is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations set forth in Paragraph 9 of the Complaint, and on that basis denies each and every one of the remaining allegations set forth therein.

10. Teva states that it is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 10 of the Complaint, and on that basis denies each and every one of the allegations set forth therein.

11. Teva admits that United States Patent No. 4,824,860 (the "'860 patent") is entitled "Treatment of Parkinsons Disease" and states on its face that it was issued on April 25, 1989, identifying David A. A. Owen, as the inventor. Teva further admits that the '860 patent states on its face that it was assigned to Smith Kline & French Laboratories, Ltd. Teva admits that the '860 patent purports to claim a method of treating Parkinson's Disease by administering an effective non-toxic amount of 4-aminoalkyl-2(3H)-indolone compounds. Teva denies that the claims of the '860 patent are valid and enforceable. Teva states that it is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations set forth in Paragraph 11 of the Complaint, and on that basis denies each and every one of the remaining allegations set forth therein.

12. Teva states that it is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 12 of the Complaint, and on that basis denies each and every one of the allegations set forth therein.

13. Teva admits that GSK sells ReQuip®, a commercial formulation of ropinirole hydrochloride. Teva further admits that GSK is identified by the United States Food and Drug Administration ("FDA") as the holder of approved New Drug Application ("NDA") No. 20-658 for ropinirole hydrochloride tablets in dosages of Eq. 0.25 mg base, 0.5 mg base, 1 mg base, 2 mg base, 3 mg base, 4 mg base, and 5 mg base. Teva states that it is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations set forth in

Paragraph 13 of the Complaint, and on that basis denies each and every one of the remaining allegations set forth therein.

14. Teva admits the allegations set forth in Paragraph 14 of the Complaint.

15. Teva admits the allegations set forth in Paragraph 15 of the Complaint.

16. Teva admits that the drug product for which its ANDA No. 77-460 seeks FDA approval contains as the active ingredient ropinirole hydrochloride. Teva admits that the Eq. 0.25 mg base, 0.5 mg base, 1 mg base, 2 mg base, 3 mg base, 4 mg base, and 5 mg base ropinirole hydrochloride tablets that are the subject of its ANDA No. 77-460 are bioequivalent to GSK's Eq. 0.25 mg base, 0.5 mg base, 1 mg base, 2 mg base, 3 mg base, 4 mg base, and 5 mg base Requip tablets within the meaning of FDA regulations. Teva further admits that its proposed labeling complies with FDA ANDA labeling requirements. Teva denies the remaining allegations set forth in Paragraph 16 of the Complaint.

17. Teva admits the allegations set forth in Paragraph 17 of the Complaint.

18. Teva admits the allegations set forth in Paragraph 18 of the Complaint.

19. Teva reiterates its responses to the allegations contained in the preceding paragraphs as if fully set forth herein.

20. Teva admits that the submission of Teva's ANDA No. 77-460 to obtain approval for the manufacture, use, offering for sale, sale or importation into the United States of Teva's ropinirole hydrochloride tablets constitutes a technical act of infringement under 35 U.S.C. § 271(e)(2)(A) sufficient for jurisdiction, but denies any allegation of infringement for any other purposes. Teva denies that the manufacture, use, offering for sale, sale or importation into the United States of Teva's ropinirole hydrochloride tablets would infringe any valid claim of the '808 patent or that its filing of its ANDA is grounds for a finding of infringement.

21. Teva admits that the submission of Teva's ANDA No. 77-460 to obtain approval for the manufacture, use, offering for sale, sale or importation into the United States of Teva's ropinirole hydrochloride tablets creates an actual case or controversy with respect the infringement of the '808 patent. Teva denies that the manufacture, use, offering for sale, sale or importation into the United States of Teva's ropinirole hydrochloride tablets would infringe any valid claim of the '808 patent. Teva further denies the remaining allegations set forth in Paragraph 21 of the Complaint.

22. Teva denies that FDA approval of the Teva's ANDA No. 77-460 will infringe any valid claim of the '808 patent. Teva further denies the remaining allegations set forth in Paragraph 22 of the Complaint.

23. Teva admits that it had knowledge of the '808 patent prior to filing Teva ANDA No. 77-460. Teva denies that this knowledge can or does form the basis for a finding of willful infringement and as such denies the remaining allegations set forth in Paragraph 23 of the Complaint.

24. Teva denies the allegations set forth in Paragraph 24 of the Complaint.

25. Teva reiterates its responses to the allegations contained in the preceding paragraphs as if fully set forth herein.

26. Teva admits that the submission of Teva's ANDA No. 77-460 to obtain approval for the manufacture, use, offering for sale, sale or importation into the United States of Teva's ropinirole hydrochloride tablets constitutes a technical act of infringement under 35 U.S.C. § 271(e)(2)(A) sufficient for jurisdiction, but denies any allegation of infringement for any other purposes. Teva denies that the manufacture, use, offering for sale, sale or importation into the

United States of Teva's ropinirole hydrochloride tablets would infringe any valid claim of the '860 patent or that its filing of its ANDA is grounds for a finding of infringement.

27. Teva admits that the submission of Teva's ANDA No. 77-460 to obtain approval for the manufacture, use, offering for sale, sale or importation into the United States of Teva's ropinirole hydrochloride tablets for the treatment of Parkinson's Disease creates an actual case or controversy with respect the infringement of the '860 patent. Teva denies that the manufacture, use, offering for sale, sale or importation into the United States of Teva's ropinirole hydrochloride tablets would infringe any valid claim of the '860 patent. Teva further denies the remaining allegations set forth in Paragraph 27 of the Complaint.

28. Teva denies that FDA approval of the Teva's ANDA No. 77-460 will infringe any valid claim of the '860 patent. Teva further denies the remaining allegations set forth in Paragraph 28 of the Complaint.

29. Teva admits that it had knowledge of the '860 patent prior to filing Teva ANDA No. 77-460. Teva denies that this knowledge can or does form the basis for a finding of willful infringement and as such denies the remaining allegations set forth in Paragraph 29 of the Complaint.

30. Teva denies the allegations set forth in Paragraph 30 of the Complaint.

First Defense

31. The manufacture, use, offering for sale, sale or importation of the ropinirole hydrochloride tablets that are the subject of Teva's ANDA No. 77-460 will not infringe any valid claim of the '808 patent.

32. Teva's filing of its ANDA No. 77-460 did not infringe any valid claim of the '808 patent.

Second Defense

33. Each of the claims of the '808 patent are invalid for failure to satisfy one or more of sections 101, 102, 103, 112 and 116 of Title 35 of the United States Code.

Third Defense

34. The manufacture, use, offering for sale, sale or importation of the ropinirole hydrochloride tablets that are the subject of Teva's ANDA No. 77-460 will not infringe any valid claim of the '860 patent.

35. Teva's filing of its ANDA No. 77-460 did not infringe any valid claim of the '860 patent.

Fourth Defense

36. Each of the claims of the '860 patent are invalid for failure to satisfy one or more of sections 101, 102, 103, 112 and 116 of Title 35 of the United States Code.

PRAYER FOR RELIEF

WHEREFORE, defendant Teva Pharmaceuticals USA, Inc. respectfully requests that:

a) The Complaint of plaintiffs Smith Kline & French Laboratories, Ltd, and SmithKline Beecham Corp., d/b/a GlaxoSmithKline, be dismissed with prejudice;

b) The filing of Teva's ANDA No. 77-460 be found not to infringe any valid claims of the '808 patent;

c) The filing of Teva's ANDA No. 77-460 be found not to infringe any valid claims of the '860 patent;

d) The manufacture, use, offering for sale, sale or importation into the United States of Teva's ropinirole hydrochloride tablets that are the subject of Teva's ANDA No. 77-460 be found not to infringe any valid claim of the '808 patent;

e) The manufacture, use, offering for sale, sale or importation into the United States of Teva's ropinirole hydrochloride tablets that are the subject of Teva's ANDA No. 77-460 be found not to infringe any valid claim of the '860 patent;

f) The '808 patent be found invalid;

g) The '860 patent be found invalid;

h) Teva be awarded its costs in this action;

i) Teva be awarded its attorneys' fees pursuant to 35 U.S.C. § 285; and

j) Teva be awarded such other and further relief as this Court may deem just and proper.

COUNTERCLAIMS

Jurisdiction and Venue

1. These counterclaims seek declaratory judgments pursuant to 28 U.S.C. §§ 2201 and 2202.

2. This Court has jurisdiction over these counterclaims pursuant to Title 35 U.S.C. and 28 U.S.C. §§ 1331 and 1338(a).

3. Venue is proper in this Court pursuant to 28 U.S.C. § 1391.

4. A justiciable controversy exists between the parties hereto with respect to validity, scope, and infringement of certain claims of U.S. Patent Nos. 4,452,808 and 4,824,860.

Acts Giving Rise to this Action

5. GSK is identified by the FDA as the holder of approved NDA No. 20-658 for ropinirole hydrochloride tablets in dosages of Eq. 0.25 mg base, 0.5 mg base, 1 mg base, 2 mg base, 3 mg base, 4 mg base, and 5 mg base.

6. GSK caused the '808 and '860 patents to be listed in the FDA publication entitled "Approved Drug Products With Therapeutic Equivalence Evaluation" (the "Orange Book") as patents which claim the drug for which GSK submitted the NDA or which claim a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug, or in the method of using the drug. GSK is also the record owner of these two patents.

7. Teva submitted its ANDA No. 77-460 to obtain FDA approval to engage in the commercial manufacture, use and sale of Eq. 0.25 mg base, 0.5 mg base, 1 mg base, 2 mg base, 3 mg base, 4 mg base, and 5 mg base ropinirole hydrochloride tablets, prior to the expiration of the '808 and '860 patents.

8. Teva sent GSK letters dated February 21, 2005 ("Notification Letters") notifying each that Teva's ANDA was received by the FDA, and that Teva's ANDA contained a "paragraph IV certification" that the '808 and '860 patents are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use, or sale of the product described in Teva's ANDA.

First Counterclaim

9. Teva reiterates the allegations contained in the preceding paragraphs as if fully set forth herein.

10. The manufacture, use, offer to sell, sale, and/or importation into the United States of the ropinirole hydrochloride tablets that are the subject of Teva's ANDA No. 77-460 will not infringe any valid claim of the '808 patent. Nor did the filing of Teva's ANDA infringe any valid claim of the '808 patent.

Second Counterclaim

11. Teva reiterates the allegations contained in the preceding paragraphs as if fully set forth herein.

12. The '808 patent is invalid for failure to satisfy the provisions of one or more of sections 101, 102, 103, 112 and 116 of Title 35 of the United States Code.

Third Counterclaim

13. Teva reiterates the allegations contained in the preceding paragraphs as if fully set forth herein.

14. The manufacture, use, offer to sell, sale, and/or importation into the United States of the ropinirole hydrochloride tablets that are the subject of Teva's ANDA No. 77-460 will not infringe any valid claim of the '860 patent. Nor did the filing of Teva's ANDA infringe any valid claim of the '860 patent.

Fourth Counterclaim

15. Teva reiterates the allegations contained in the preceding paragraphs as if fully set forth herein.

16. The '860 patent is invalid for failure to satisfy the provisions of one or more of sections 101, 102, 103, 112 and 116 of Title 35 of the United States Code.

PRAYER FOR RELIEF

WHEREFORE, defendant Teva Pharmaceuticals USA, Inc. respectfully requests that:

a) The filing of Teva's ANDA No. 77-460 be declared not to infringe any valid claims of the '808 and '860 patents;

b) The manufacture, use, offer to sell, sale, and/or importation into the United States of Teva's ropinirole hydrochloride tablets that are the subject of Teva's ANDA No. 77-460 be declared not to infringe any valid claims of the '808 and '860 patents;

c) The '808 patent be declared invalid;

d) The '860 patent be declared invalid;

e) Teva be awarded its costs in this action;

f) Teva be awarded its attorneys' fees pursuant to 35 U.S.C. § 285; and

g) Teva be awarded such other and further relief as this Court may deem just and proper.

Respectfully submitted,

Josy W. Ingersoll (#1088)
YOUNG CONAWAY STARGATT & TAYLOR, LLP
The Brandywine Building
1000 West Street, 17th Floor
P.O. Box 391
Wilmington, Delaware 19899-0391
(302) 571-6600
jingersoll@ycst.com

Jay P. Lefkowitz
Karen M. Robinson
Steven A. Engel
Stephen D. Dove
KIRKLAND & ELLIS LLP
655 15th Street, N.W.
Washington, D.C. 20005-5793
(202) 879-5000

Attorneys for Teva Pharmaceuticals USA, Inc.

Dated: April 26, 2005

CERTIFICATE OF SERVICE

I, Josy W. Ingersoll, Esquire, hereby certify that on April 26, 2005, I caused to be electronically filed a true and correct copy of the foregoing document with the Clerk of the Court using CM/ECF, which will send notification that such filing is available for viewing and downloading to the following counsel of record:

Patricia Smink Rogowski, Esquire
Connolly Bove Lodge & Hutz LLP
The Nemours Building
1007 North Orange Street
Wilmington, DE 19801

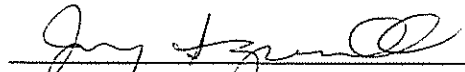
I further certify that on April 26, 2005, I caused a copy of the foregoing document to be served by hand delivery on the above-listed counsel of record and on the following non-registered participants in the manner indicated:

BY FEDEX

William F. Lee, Esquire
Wilmer, Cutler, Pickering, Hale and Dorr LLP
60 State Street
Boston, MA 02109

William G. McElwain, Esquire
Wilmer, Cutler, Pickering, Hale and Dorr LLP
The Willard Office Building
1455 Pennsylvania Avenue, N.W.
Washington, D.C. 20004

YOUNG CONAWAY STARGATT & TAYLOR, LLP



Josy W. Ingersoll (No. 1088)
The Brandywine Building
1000 West Street, 17th Floor
Wilmington, Delaware 19801
(302) 571-6600
jingersoll@ycst.com

Attorneys for Defendant